Atty. Docket No. TAK003 P323

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Art Unit	:	1651
Examiner	:	Francisco C. Prats
Applicants	:	Yoshihito Ikeda et al.
Appln. No.	:	10/018,770
Filing Date	:	December 17, 2001
Confirmation No.	:	2012
For	:	DRUG COMPOSITION CONTAINING A LECITHIN-MODIFIED SUPEROXIDE DISMUTASE

PAPER CORRECTING THE APPEAL BRIEF'S SUMMARY OF CLAIMED SUBJECT MATTER UNDER 37 C.F.R. § 41.37(c)(1)(v)

In reply to the Notification of Non-Compliant Appeal Brief mailed August 5, 2009, and to the Order Returning Undocketed Appeal to Examiner dated July 31, 2009, Appellant submits in accordance with MPEP § 1205.03 and 37 C.F.R. § 41.37(c)(1)(v) the attached paper providing a Summary of the Claimed Subject Matter.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to a drug composition comprising sucrose and a lecithin-modified superoxide dismutase. Details regarding the meaning of a lecithin-modified superoxide dismutase (also as known as phosphatidylcholine-modified superoxide dismutase or PC-SOD) are provided at page 3, lines 1-12 of the specification, and from page 6, line 16 through page 10, line 14 of the specification. Combining the lecithin-modified superoxide dismutase with sucrose is described in detail at page 11, lines 6-22 of the specification.

Independent claim 19 is directed to a composition containing a lecithin-modified superoxide dismutase that is reconstitutable from a dry form and which has been stabilized against degradation due to cleavage within the lecithin moieties. Lecithin-modified superoxide dismutase (PC-SOD) is described in detail at page 3, lines 1-12 of the specification and from page 6, line 16 through page 10, line 14 of the specification. A lyophilized (freeze-dried) composition that is in a reconstitutable dry form is described, for example, at page 15, lines 6-12 of the specification, and at page 25, line 23 through page 26, line 1 of the specification. Additionally, the composition is stabilized against degradation due to cleavage within the lecithin moieties. Stabilization against degradation due to cleavage within the lecithin moieties is described, for example, at page 16, lines 12-25 of the specification. The composition comprises lyophilized lecithin-modified superoxide dismutase and sucrose in an amount that is effective to stabilize the lecithin-modified superoxide dismutase against degradation due to cleavage within the lecithin. Lyophilization of lecithin-modified superoxide dismutase is described, for example, at page 13, line 19 though page 14, line 24 of the specification. The addition of sucrose in an amount that is effective to stabilize the lecithin-modified superoxide dismutase against degradation due to cleavage within the lecithin is described, for example, at page 21, line 23 through page 22, line 24. Claim 19 further specifies that the composition as claimed achieves a stabilization whereby there is not any observable difference in the amount of degradation products before lyophilization and after re-dissolution, and wherein the composition completely dissolves in water in less than ten seconds. Cases where no substantial difference was observed between peak shapes of PC-SOD before and after lyophilization, indicating that there is not an observable difference in the amount of degradation products before and after lyophilization and re-dissolution, are discussed at page 26, lines 16-22 of the specification. Such compositions that dissolve in water in less than ten seconds are described, for example, at page 25, lines 11-19 of the specification.

Respectfully submitted,

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Date

/Gunther J. Evanina/
Gunther J. Evanina, Registration No. 35502
Price, Heneveld, Cooper, DeWitt & Litton, LLP
695 Kenmoor, S.E.
Post Office Box 2567
Grand Rapids, Michigan 49501
(616) 949-9610

GJE/ktr